

In re Application of: FOGH, et al.

Serial No.: 09/601,138

Filed: October 26, 2000

For: METHOD FOR TREATING ACUTE INTERMITTENT PORPHYRIA...

Confirmation No.: 1652

Art Unit: 1652

Examiner: WALICKA, M.

Washington, D.C.

Atty.'s Docket: FOGH-1

Date: March 26, 2004

U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202
Sir:

Transmitted herewith is an [XX] Amendment [XX] Exs. A-1 to A-8 (NIH database extracts) in the above-identified application. [XX] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
[] Small entity status of this application under 37 CFR 1.9 and 1.27 has been previously asserted.
[] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
[] No additional fee is required.

The fee has been calculated as shown below:

| | (Col. 1) | | (Col. 2) | (Col. 3) | | Small Entity | | Other Than a Small Entity | |
|--|----------------------------------|-------|---------------------------------|---------------|--|--------------|----------------|---------------------------|----------------|
| | Claims Remaining After Amendment | | Highest No. Previously Paid For | Present Extra | | Rate | Additional Fee | Rate | Additional Fee |
| Total | 37 | Minus | 44 | 0 | | x 9 | \$ | x18 | \$ |
| Indep. | 4 | Minus | 4 | 0 | | x43 | \$ | x86 | \$ |
| First Presentation of Multiple Dependent Claim | | | | | | 145 | \$ | +290 | \$ |
| TOTAL ADDITIONAL CLAIMS FEE | | | | | | | \$ | Total | \$ |

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col.1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required applicant requests that this be considered a petit

[XX] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity

Response Filed Within

[] First - \$ 55.00

[] Second - \$ 210.00

[XX] Third - \$ 475.00

[] Fourth - \$ 740.00

[] Fifth - \$1005.00

Other Than Small Entity

Response Filed Within

[] First - \$ 110.00

[] Second - \$ 420.00

[] Third - \$ 950.00

[] Fourth - \$1480.00

[] Fifth - \$2010.00

[] Less fees (\$) already paid for months extension of time on

[] Please charge my Deposit Account No. 02-4035 in the amount of \$. A duplicate copy of this sheet is attached.

[] A check in the amount of \$ is attached (check no.).

[XX] Credit Card Payment Form, PTO-2038, authorizing payment in the amount of \$475.00 is attached.

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR Section 1.16 and all patent processing fees under 37 CFR Section 1.17 throughout the prosecution of the case.

This blanket authorization does not include patent issue fees under 37 CFR Section 1.18.

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

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Telephone: (202) 628-5197

By:

[Signature]
LYNN P. COOPER
Registration No. 28,005

COPY



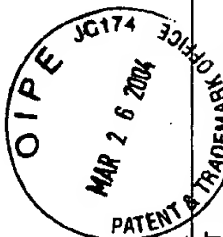
APPLICATION/PATENT NO: 09/001,138

DOCKET NO: Fogh=1

THE PATENT AND TRADEMARK OFFICE STAMP
HEREON ACKNOWLEDGES RECEIPT OF THE
FOLLOWING PAPERS:

- ☒ FEES \$ 475.00 ☐ PTO FORM 2038 ☐ (CH. # 3 MONTHS)
- ☒ EXTENSION OF TIME
- ☒ TRANSMITTAL LETTER
- ☐ MISSING PARTS RESPONSE WITH DECL
- ☒ AMENDMENT/RESPONSE (circle one)
- ☐ PRELIMINARY ☐ SUPPLEMENTAL
- ☐ APPLICATION DATA SHEET
- ☐ RESTRICTION/ELECTION REPLY
- ☐ SEQUENCE LISTING ☐ WITH DISK
- ☐ RCE TRANSMITTAL
- ☐ NOTICE OF APPEAL
- ☐ APPEAL BRIEF (TRIPPLICATE)
- ☐ REPLY BRIEF (TRIPPLICATE)
- ☒ OTHER Exs. A-1 to A-8 (NIH database extracts)

CONF. NO.: 5676
CLIENT CODE: PLOU



- ☐ ASSIGNMENT
- ☐ INFORMATION DISCLOSURE STATEMENT
- ☐ FORM SB08A & PATENTS/PUBS
- ☐ PRIORITY DOCUMENT(S) NO. _____
- ☐ DECLARATION UNDER \$ _____
- ☐ SHEETS OF FORMAL DRAWINGS
- ☐ ISSUE FEE TRANSMITTAL FORM
- ☐ PUBLICATION FEE
- ☐ MAINTENANCE FEE LETTER



1652

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---------------------------------|---|------------------------|
| In re Application of: |) | Art Unit: 1652 |
| |) | |
| FOGH, et al. |) | Examiner: WALICKA, M. |
| |) | |
| Serial No.: 09/601,138 |) | Washington, D.C. |
| |) | |
| Filed: October 26, 2000 |) | April 27, 2004 |
| |) | |
| For: METHOD FOR TREATING ACUTE) | | Docket No.: FOGH=1 |
| INTERMITTENT PORPHYRIA) | | |
| (AIP) AND OTHER... |) | Confirmation No.: 5676 |

REQUEST TO VACATE ERRONEOUS HOLDING OF ABANDONMENT

U.S. Patent and Trademark Office
2011 South Clark Place
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Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

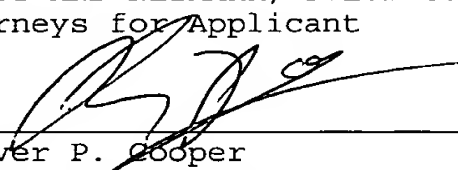
S i r :

Applicants hereby request that the notice of abandonment mailed April 20, 2004 be vacated, as it ignores the response timely filed on March 26, 2004, as evidenced by the attached mailroom receipt. A courtesy copy of the March 26 response is also enclosed. Please note that the courtesy copy of the response includes a copy of the original credit card payment form. Care should be taken that we are not charged twice for the same fees.

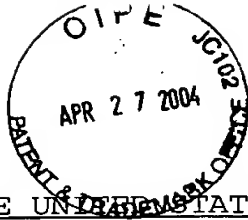
Two additional papers are being filed today: Third IDS; and Supplemental Response (with exhibit).

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: 
Iver P. Cooper
Reg. No. 28,005

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| INTERMITTENT PORPHYRIA) |) | |
| (AIP) AND OTHER... |) | Confirmation No.: 5676 |

SUPPLEMENTAL RESPONSE

U.S. Patent and Trademark Office
2011 South Clark Place
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Arlington, Virginia 22202

S i r :

As evidence that applicants' invention satisfies the long felt but hitherto unmet need for a more effective treatment of acute intermittent porphyria, we submit a copy of a clinical study report:

HemeBiotech A/S "A dose escalating, open label rhPBGD single dose (Part A) and double blind, randomised, placebo controlled repeated dose (Part B), pharmacokinetic, efficacy (biochemical), safety and tolerability trial of i.v. rhPBGD in healthy subjects with and without diagnosed manifest acute intermittent porphyria (AIP), subReport to Final Integrated Clinical Trial Report, Trial Phase:I-II (December 3, 2003).

The treatment group, of otherwise healthy AIP subjects, received recombinant human PBGD. The effect was to reduce urine and plasma PBG levels, with the duration of the effect being

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dependent on the dosing schedule (cp. Figs. 9-1 to 9-1). AIP is caused by elevated PBG and ALA (Spec. P2, L20-25).

Respectfully submitted,

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Attorneys for Applicant

By: 

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Enclosure
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